K090501
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Biopsy Sciences

MAR - 5 2009

SPECIAL 510(K) SUMMARY (21 CFR 807.92)

HYDROMARK BIOPSY SITE MARKER

510(k) Owner: Biopsy Sciences, Inc.
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Clearwater, FL 33760
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Contact Person: Sharon Rockwell
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Date Prepared: February, 2009

Trade Name: HydroMark Breast Biopsy Site Marker

Common Name: Biopsy site marker

Classification Name: Implantable clip per 21 CFR 878.4300, NEU

Predicate Devices: Biopsy Sciences HydroMark Breast Biopsy Site Marker, K060769 and K083006

Device Description: The Biopsy Sciences HydroMark Breast Biopsy Site Markers are made of desiccated hydrogel embedded with either a stainless steel or titanium coil. The HydroMark is visible under mammography, ultrasound and magnetic resonance imaging. It expands in the void created during biopsy and does not migrate. The hydrogel material degrades in a manner similar to absorbable sutures, via hydrolysis.

The HydroMark Site Marker is currently provided pre-loaded in a sterile, disposable, flexible plastic syringe-like applicator that is compatible with the J&J Ethicon Endo-Surgery Mammotome probe. Two modified applicators have been developed which are both 15 gauge stainless steel syringe-like applicators. One has cm markings and a beveled tip to aid in needle placement by direct puncture, or to fit inside a 13 gauge or larger coaxial needle. The distal tip of the applicator is etched to enhance its visibility under ultrasound guidance. An additional stainless steel applicator has

been developed to be compatible with the Suros 12 gauge biopsy system. The hydrogel portion of the HydroMark Breast Biopsy Site Marker has a dimensional change to accommodate the 15 gauge applicators, which by design create smaller cavities. The titanium and stainless steel coils embedded in the hydrogel are identical to the original device.

Intended Use:

The Biopsy Sciences, Inc. HydroMark Breast Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

The indications for use are identical to those of the predicate device, the Biopsy Sciences HydroMark Breast Biopsy Site Marker provided in an applicator for the Mammotome device.

Technological Characteristics:

The HydroMark Breast Biopsy Site Markers, regardless of the applicators in which they are provided, have the same indications for use, principles of operation, materials and technological characteristics. The hydrogel component expands on fluid contact to fill the void created during the biopsy, leaving the HydroMark at the exact location of biopsy. Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal metallic coil which provides permanent visibility under x-ray and MRI.

The only modifications from the predicate device are: 1) a change from the plastic syringe-like applicator to a stainless steel syringe-like applicator with etched depth markings, an echogenic distal end for ultrasound visualization, and a ground tip for direct placement or placement through a 13 gauge coaxial needle, 2) a longer version of the stainless steel syringe-type applicator with a blunt tip that will accommodate the Suros ATEC™ 12 STX gauge biopsy device, and 3) a change in the outer diameter of the HydroMark hydrogel component to accommodate the 15 gauge applicator, which by design produce smaller biopsy cavities.

Non-Clinical Performance Data:

Risk analysis relevant to the design modifications identified tests related to the compatibility of the HydroMark Site Markers with the applicators, and the compatibility of the applicators with coaxial needles and the Suros biopsy device. These tests, in addition to the applicable design verification and validation tests performed on the original device, were conducted and established

that the HydroMark Breast Biopsy Site Markers in their modified applicators meet the design input criteria.

Conclusions:

The HydroMark Breast Biopsy Site Markers supplied pre-loaded in a stainless steel applicator for insertion directly or through a coaxial needle, and supplied pre-loaded in a stainless steel applicator compatible with the Suros ATEC™ 12 STX gauge biopsy device have the same indications for use, and are similar in design, functionality, and technological characteristics as the predicate device to support a substantially equivalent determination. The modifications identified are minor in nature and do not raise any new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2009

Biopsy Sciences, LLC
% Ms. Sharon Rockwell
Regulatory Affairs
5582 Chalon Road
Yorba Linda, California 92886

Re: K090501
Trade/Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: February 10, 2009
Received: February 25, 2009

Dear Ms. Rockwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090501

Device Name: Biopsy Sciences HydroMark Breast Biopsy Site Marker

Indications for Use:

The Biopsy Sciences LLC., HydroMark Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM 3/4/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090501